IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of	:	**Confirmation No. 2005**
Eric COSSEMENT et al.	:	Docket No. 2003_1709
Serial No. 10/724,640	:	Group Art Unit 1624
Filed December 2, 2003	:	Examiner Emily B. Bernhardt

ENANTIOMERS OF 1-[(4-CHLOROPHENYL) PHENYLMETHYL)-4-[(4-METHYLPHENYL) SULFONYL]PIPERAZINE

Mail Stop: Amendment

PATENT OFFICE FEE TRANSMITTAL FORM

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Attached hereto is a check in the amount of $420.00 to cover Patent Office fees relating to filing the following attached papers:

Petition for Extension of Time $420.00

A duplicate copy of this paper is being submitted for use in the Accounting Division, Office of Finance.

The Commissioner is authorized to charge any deficiency or to credit any overpayment associated with this communication to Deposit Account No. 23-0975, with the EXCEPTION of deficiencies in fees for multiple dependent claims in new applications.

Respectfully submitted,

Eric COSSEMENT et al.

THE COMMISSIONER IS AUTHORIZED TO CHARGE ANY DEFICIENCY IN THE FEE FOR THIS PAPER TO DEPOSIT ACCOUNT NO. 23-0975.

By _____
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September 7, 2004

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RESPONSE

THE COMMISSIONER IS AUTHORIZED TO CHARGE ANY DEFICIENCY IN THE FEE FOR THIS PAPER TO DEPOSIT ACCOUNT NO. 23-0975.

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Official Action of April 7, 2004, a petition for a two month extension of time and the requisite fee therefor being submitted concurrently herewith, further and favorable reconsideration is respectfully requested in view of the following remarks.

The claims of the application are directed to certain specific chemical enantiomers and salts thereof, pharmaceutical compositions containing these enantiomers and salts and to pharmaceutical methods of using the enantiomers or salts.

Claims 9, 11 and 13 constitute one set of claims. These claims are directed to the substantially pure enantiomer dextrorotatory 2[2-[4-[(4-chlorophenyl)phenylmethyl]-1-piperazinyl]ethoxy]acetamide or a pharmaceutically acceptable salt thereof. See Compound L at page 25 of the specification and which is prepared in Example 5.10 spanning pages 19 and 20.

Claims 10, 12 and 14 constitute a second set of claims and are directed to the corresponding levorotatory enantiomer or pharmaceutically acceptable salt which is Compound K at page 25 and which is prepared in Example 5.9.

The composition and methods of use disclosure for the enantiomers is seen in the section "2. Peripheral Antihistaminic Properties." at pages 27 to 29 and "5. Posology and administration." at page 32.

Thus, the invention provides the substantially pure levorotatory and dextrorotatory enantiomers and their pharmaceutically acceptable salts as well as pharmaceutical compositions of each substantially free of the other. The levorotatory enantiomer or salt is employed to inhibit the effects of histamine in a patient by applying to the skin or mucous membrane of the patient. The dextrorotatory enantiomer or salt is administered to treat allergic conditions in a patient while avoiding undesirable effects on the central nervous system.

The claims are rejected under 35 U.S.C. § 103(a) as being unpatentable over the Baltes reference (US '358) and Applicants' admissions of record. Applicants submit that the rejection is untenable, and they traverse the rejection.

The initial point to be noted is that the claims specify the substantially pure dextrorotatory and levorotatory enantiomers. This means a purity of greater than 98%. See page 3 of the specification, the last full paragraph. Prior to the present invention, the art-skilled were not enabled to prepare the individual enantiomers of the known racemic mixtures in this degree of required purity. In this respect see the disclosure at pages 1 to 3 of the specification. At the time of the invention, a process for the preparation of final product enantiomers was described in the British Patent No. 2,225,321. But, as stated in the instant specification, that process suffered from the disadvantage that it did not enable the preparation of the enantiomers in the desired degree of purity. Applicants discovered a new route involving new intermediates which has enabled the preparation of the final product enantiomers in the desired degree of purity. That being the case, it cannot be said that the substantially pure enantiomers as claimed herein would be obvious to one skilled in the art from the disclosure of the racemic mixture (Baltes '358) and Applicants' admission that the process of the British patent was known. Furthermore, since the individual enantiomers in the requisite degree of purity are themselves not obvious to one skilled in the art, it follows that pharmaceutical compositions containing them and methods of using them likewise cannot be considered as obvious under 35 U.S.C. § 103(a).

The Examiner has taken the position that since the racemic mixture of the enantiomers is known, it is incumbent upon Applicants not only to establish an unexpected difference between the individual enantiomers themselves but also to establish an unexpected difference to exist between each of the individual enantiomers and the racemate. The Examiner does not appear to contest the surprising nature of Applicants' discovery of the activities of the two enantiomers relative to each other.

Applicants submit that any insistence upon a comparison of the individual enantiomers with the racemate in the present situation is wrong. In such a comparison, the qualitative differences between the enantiomers would not be discernable as the racemate would possess the combined properties of the individual enantiomers. This qualitative unexpected difference in properties only becomes apparent on comparison of the two enantiomers with each other.

It is also pointed out that the Examiner's characterization of the data relied upon is misleading in that it fails to acknowledge the qualitative difference asserted, especially with respect to the locally acting enantiomer.

Applicants thus respectfully submit that the rejection of claims 9-14 under 35 U.S.C. § 103(a) is not proper and should be withdrawn.

In view of the foregoing, Applicants respectfully submit that the present application is in condition for allowance and such allowance is solicited.

Respectfully submitted,

Eric COSSEMENT et al.

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